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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,505	06/28/2001	Saluh Kivlighn	50193-109	4997
7590	03/13/2006		EXAMINER	
McDERMOTT, WILL & EMERY 600 13th Street, N.W. Washington, DC 20005-3096			KANTAMneni, SHOBHA	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/892,505	KIVLIGHN ET AL.
	Examiner Shobha Kantamneni	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5,7 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) NONE is/are allowed.
- 6) Claim(s) 1,5, 7, 14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

The Amendment filed on 10/07/2005, canceled claim 15.

The amendment filed on 10/07/2005 which cancelled claim 15, is sufficient to overcome the rejections of Claim 15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments have been fully considered, but not found persuasive, and the rejection of claims 1, 5, 7, 14 under 35 U.S.C. 112, first paragraph is MAINTAINED, because the specification, while being enabling for a method of treating hypertension, **does not reasonably provide enablement for a method of preventing hypertension.**

Applicant's arguments have been fully considered, but not found persuasive, and the rejection of claims 1, 5 under 35 U.S.C. 112, first paragraph is MAINTAINED, because the specification, while being enabling for xanthine oxidase inhibitor such as allopurinol and carprofen for the treatment of hypertension, **does not reasonably provide enablement for any substance or compounds represented by xanthine oxidase inhibitor in general.** See under response to arguments.

Applicant's arguments have been fully considered but not found persuasive, and the rejection of claims 1, 5 under 35 U.S.C. 102(b) as being anticipated by Baldwin (US 4,058,614) is MAINTAINED. See under response to arguments.

Applicant's arguments have been fully considered, but not found persuasive, and the rejection of claims 1, 5, 7, 14, under 35 U.S.C. 102(b) as being anticipated by Miyamoto et al. (Proceedings of the Society for Experimental Biology and Medicine 1996, 211(4), 366-73) is MAINTAINED. See under response to arguments.

Claims 1, 5, 7, and 14 are pending.

Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 7, 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating hypertension, **does not reasonably provide enablement for a method of preventing hypertension**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention **commensurate in scope** with these claims.

The claims are directed to a method and a composition for treating or **preventing** hypertension. The specification fails to adequately teach how to use the herein claimed method and composition **for preventing hypertension**.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention:

The rejected claims are drawn to a method and a composition consisting essentially of xanthine oxidase inhibitor for treating or **preventing hypertension**.

(2) Breadth of the Claims:

The instant claims embrace a composition containing a variety of xanthine oxidase inhibitors for treating or **preventing** hypertension.

(3) Guidance of the Specification / Working Examples:

In the instant case, **no** working examples are presented in the specification as filed showing how to **prevent** hypertension in a patient in need of such treatment totally, absolutely, or permanently, not even occurring at the first time.

(4) State/predictability of the Art:

The relative skill of those in the art is high.

However the predictability is low. "To prevent" actually means to anticipate or counter in advance, to keep from happening etc. (as per Webster's II Dictionary). It is well-known in the state of the art that the cause of hypertension is multifactorial, that is,

there are several factors whose combined effects produce hypertension. Hypertension may result from age related changes, environmental toxins, side effects by administration of drugs, genetic factors, high uric acid levels (hyperuricemia) etc. These conditions are caused by various etiologies. For example, hypertension may be due to hyperuricemia, which can be caused by side effects due to administration of cyclosporine. Thus by treating one condition such as hyperuricemia, one cannot prevent hypertension from occurring. The current known treatment of hypertension depends on the patient populations and the severity of the disorders. Some of the disorders, such as primary hypertension, have no known etiology (See Merck manual, page 413). Thus the skilled artisan would view that the **prevention** of hypertension in a patient in need of such treatment totally, absolutely or permanently is highly unpredictable using the composition containing xanthine oxidase inhibitor.

(5) The Quantity of Experimentation Necessary:

There is no working example provided for the prevention of hypertension. Therefore, Applicant fails to provide information sufficient to practice the claimed invention, absent **undue experimentation**.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed

above, to practice the claimed invention herein, a person of skill in the art would have to test a variety of xanthine oxidase inhibitors in the instant claims to be administered to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Accordingly the claims are evaluated as method of treating hypertension and not method of **preventing** hypertension.

Response to Arguments:

Applicant's argument that "The data presented in Figures 3A and 3B demonstrate that the xanthine oxidase inhibitor, allopurinol, prevents hypertension in a rat model of the disease. Control rats placed on a mild salt restriction diet have a fall in blood pressure after several weeks. This is prevented when the diet also contains oxonic acid, which is shown in Figure 2 to elevate blood pressure in rats. However, rats placed on diets containing oxonic acid, low salt and allopurinol, do not show an increase in blood pressure, i.e., hypertension was prevented. Thus, the present specification enables claims to methods of both preventing and treating hypertension using a xanthine oxidase inhibitor of the invention." This argument is not persuasive because the cause of hypertension is multifactorial such as side effects by administration of drugs genetic factors, high uric acid levels, salt content of the body etc, and are caused by various etiologies. Allopurinol, a xanthine oxidase inhibitor reduces hypertension by reducing uric acid levels. Thus, by treating one condition such as hyperuricemia, one cannot prevent hypertension from occurring. Note that on page 1, lines 22-25, it is taught that only 25 to 50% of hypertensive individuals have elevated serum uric acid. Thus the

skilled artisan would view that the **prevention** of hypertension in a patient in need of such treatment totally, absolutely or permanently not even occurring at the first time is highly unpredictable using the composition containing xanthine oxidase inhibitor.

Thus, the claims are evaluated as method of treating hypertension and not method of **preventing** hypertension.

Claims 1, 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for xanthine oxidase inhibitor such as allopurinol and carprofen for the treatment of hypertension, **does not reasonably provide enablement for any substance or compounds represented by xanthine oxidase inhibitor in general.** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention **commensurate in scope** with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation.** Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the

claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating hypertension by administering xanthine oxidase inhibitor. The nature of the invention is complex in that it encompasses the treatment of hypertension comprising administering **any xanthine oxidase inhibitor**.

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass treatment of hypertension by administering **any xanthine oxidase inhibitor**.

(3). Guidance of the Specification / (4) Working Examples:

The guidance given by the specification as to what type of xanthine oxidase inhibitor would be effective for the treatment of hypertension is limited. The only examples provided are with a xanthine oxidase inhibitor allopurinol. See page 21, EXAMPLE 2; page 22, EXAMPLE 3.

(5). State of the Art:

While the state of the art is relatively high with regard to specific xanthine oxidase inhibitor for the treatment of hypertension, the state of the art with regard to xanthine oxidase inhibitors in **general** is underdeveloped. Different xanthine oxidase inhibitor have different chemical structures and are expected to behave in different manners,

evidence that the level of skill in this art is low relative to the difficulty of the task of determining a suitable xanthine oxidase inhibitor for the treatment of hypertension.

(6). Predictability of the Art:

The invention is directed to xanthine oxidase inhibitor **in general** for the treatment of hypertension. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970).

It is further noted that the pharmaceutical art is **unpredictable**, requiring each embodiment to be individually assessed for physiological activity. For example it is known in the art that oxypurinol (also known as alloxanthine) a xanthine oxidase inhibitor is a uric acid lowering agent. The effect of xanthine oxidase inhibitors such as 4-amino-6-hydroxypyrazolo[3,4-d]pyrimidine(AHPP), allopurinol and oxypurinol on blood pressure was studied by Miyamoto et al. (Proceedings of the Society for Experimental Biology and Medicine 1996, 211(4), 366-73) in animal model. It was reported that AHPP reduced the blood pressure of SHR rats to 70 % of the initial pressure; this is almost the blood pressure of normal rats, whereas only 10 % reduction of hypertension was observed with iv injection of oxypurinol(alloxanthine). Thus even the structurally closely related uric acid lowering agent, a xanthine oxidase inhibitor, such as AHPP, and oxypurinol have very different ability of treating hypertension. Thus in the instant case, it is highly **unpredictable** to treat hypertension using **any** xanthine oxidase inhibitor or **any** uric acid lowering agent. Also one skilled in the art would recognize that it is highly

unpredictable with regards to not only therapeutic effects, but also side effects, and especially serious toxicity due to drug accumulation or that may be generated by drug-drug interactions when and/or after administering to a host any agents represented by either a xanthine oxidase inhibitor and/or while the patient also administers other medicines. One of skill in the art would not be able to fully predict the possible treatment of hypertension herein and possible adverse effects occurring with many agents having the claimed functional properties. Thus, the instant claimed invention is highly unpredictable.

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a specific xanthine oxidase inhibitor, a pharmaceutical carrier, a dosage for each xanthine oxidase inhibitor, the duration of treatment, route of treatment, etc. One of skill in the art would then need to test specific xanthine oxidase inhibitor in the model system to determine whether or not it is effective for treating hypertension and one would need to test for side effects and toxicity. If the treatment is unsuccessful, one of skill in the art would have to modify the first xanthine oxidase inhibitor, dosage, duration of treatment, route of administration, etc. Even if successful, however, one of skill in the art would then need to determine the magnitude of the side effects and toxicity of utilizing xanthine oxidase inhibitor. One of skill in the art would then need to determine whether or not the magnitude of the side effects could be reduced by increasing or decreasing the dosage of xanthine oxidase inhibitor while retaining the functional aspect. Once the functionality to toxicity ratio was maximized, one of skill in the art

would need to determine whether or not the xanthine oxidase inhibitor which had been used was of sufficient benefit that it would serve as useful for treating hypertension. If not, one would need to select another xanthine oxidase inhibitor agent and repeat the process until a sufficient benefit to detriment ratio had been achieved.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague Necessary:

Further, the recitation "xanthine oxidase inhibitor" may broadly encompass those known and unknown compounds having the recited functions as of the instant filing date, as discussed above. Note those future known compounds yet to be discovered and/or made. Hence, those unknown or future known compounds encompassed by claim 1, 5, 7, 14 herein must require to additional or future research to discover, establish or verify their usefulness. Therefore, as indicated above the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

Response to Arguments:

Applicant argues that "Applicant has discovered that use of compounds that lower uric acid levels, xanthine oxidase inhibitors or other uric acid lowering compounds, is sufficient to lower blood pressure. Thus, the specification provides an enabling disclosure for use of the claimed class of compounds which are known in the art to lower uric acid levels". This argument is not persuasive. As discussed in the

previous office action different xanthine oxidase inhibitors have different chemical structures and are expected to behave in different manners, evidence that the level of skill in this art is low relative to the difficulty of the task of determining a suitable xanthine oxidase inhibitor for the treatment of hypertension.

The recitation "xanthine oxidase inhibitor" is seen to be merely functional language.

It is further noted that the claims attempt to limit the scope of the claims by the function of the compound as opposed to the structure of the compound. While these claims may actually limit the types of compounds that may be used in the instant invention, one of ordinary skill in the art would not be apprised of how these limitations limited the scope of the structure of the compounds useful therein. Furthermore, the skilled artisan would have to undergo undue experimentation to not only determine which xanthine oxidase inhibitors that may be encompassed by the claims, but would also be subjected to the undue experimentation of determining, for example, any natural or synthetic xanthine oxidase inhibitor.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate." The CAFC further clearly states '[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter

sufficient to distinguish it from other materials" at 1405 (emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. ' A definition by function, as we have previously indicated, does not suffice to define the genus ..." at 1406 (empahasis added).

In the instant case, "xanthine oxidase inhibitor," recited in the instant claims is purely a functional distinction. Hence, these functional recitations read on any compounds that might have recited functions. However, the specification merely provides a limited number of examples of compounds such as allopurinol, carprofen for the various kinds of functional compounds possible.

Thus, Applicant's functional language at the points of novelty fail to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicant's, neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited monopoly asserted." *General Electric Co. v. Wabash Appliance Corp.* 37 USPQ at 468 (US 1938).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 (b) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldwin (US 4,058,614), rejection of record.

The instant invention is drawn to a method of treating hypertension comprising administering a composition comprising essentially of an xanthine oxidase inhibitor, and a composition comprising a xanthine oxidase inhibitor.

Baldwin discloses specific novel imidazole compounds which are active as xanthine oxidase inhibitors useful in a method of treatment of hypertension. A pharmaceutical composition for inhibiting xanthine oxidase comprising these novel substituted imidazole compounds is also disclosed. See column 1, lines 7-33; column 9, claim 14.

Response to Arguments:

Applicant argues that the patent by Baldwin does not disclose the presently claimed invention, i.e., the use of xanthine oxidase inhibitors to treat or prevent hypertension. This argument is not persuasive because Baldwin discloses substituted imidazole compounds, and also discloses that these substituted imidazole compounds are useful as xanthine oxidase inhibitors. It is further taught that the composition comprising these substituted imidazole compounds are useful in the treatment of hypertension. See column 1, lines 16-34; see column 8-column 9, claims 7, and 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyamoto et al. (Proceedings of the Society for Experimental Biology and Medicine 1996, 211(4), 366-73), rejection of record.

Miyamoto et al. discloses the inhibition of xanthine oxidase by three types of pyrazolopyrimidine derivatives. Kinetic studies indicated that allopurinol inhibited the conversion of xanthine to uric acid catalyzed by xanthine oxidase. See page 368, left bottom paragraph. A composition containing allopurinol in 1 ml of 0.1 N NaOH is also taught. See page 368, lines 16-20. Miyamoto further teach a method of treating hypertension in spontaneously hypertensive rats. Treatment with allopurinol at a dose of 45.4 mg/kg showed decrease in blood pressure. See page 370, right hand column, lines 8-11.

It is respectfully pointed out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or

components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Response to Arguments:

Applicant's argument that "Miyamoto demonstrating that allopurinol provides only a transient decrease in blood pressure is a teaching away from the claimed invention. A transient decrease in hypertension indicates that the drug, allopurinol, does not work to prevent or treat hypertension" is not persuasive. It is respectfully pointed out that Miyamoto teaches that allopurinol inhibits xanthine oxidase, and also teaches that when allopurinol was administered to rats showed decrease in blood pressure, and thus allopurinol can be useful in the treatment of hypertension.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

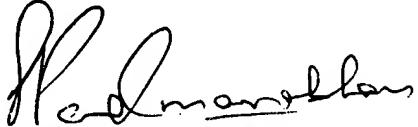
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 7.30am-4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617



SREENI PADMANABHAN
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